

SYNOPSIS

Rule 111-2-2-.41

Specific Review Considerations for Positron Emission Tomography Units.

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment is to modify an existing regulation in light of changes in the nature and delivery of positron emission tomography (PET) services. The rule modifies the standards that would be applicable to the review of applications for certificate of need for the establishment of new PET services or the expansion of existing services. The proposed rule defines a need methodology to determine when such services are needed and expounds upon the general statutory review considerations relating to relationship to the existing healthcare delivery system, existing alternatives, financial accessibility, costs to payors, financial feasibility, and consistency with the State Health Plan and modifies the existing service-specific review considerations relating to PET services.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

The existing regulation, 111-2-2-.41 is modified as follows:

The proposed rule adds standards to the applicability section of the existing rules at 111-2-2-.41(1) to clarify that on or after January 1, 2008,

- the Department shall only consider and approve applications for certificate of need for dual modality PET units,
- that the appropriate applicant for a mobile dual modality PET unit will be a hospital or DTRC at which site the mobile services will be provided, that a mobile provider shall only be required to obtain a CON to acquire the PET equipment and only when the cost to do so exceeds the equipment threshold, and
- that a certificate of need issued for mobile services shall only be valid for the provision of mobile services and not for fixed services.

At 111-2-2-.41(2)(c), the definition of "expansion" has been revised to reflect that CONs will be issued to the hospital or DTRC and not to the mobile provider.

The definition of "mobile unit" has been revised at 111-2-2-.41(2)(e) to remove the condition that mobile units must be shared amongst two or more sites, to remove the condition that mobile units must serve an existing site for at least three days per month, to allow a mobile unit to be at a site for up to sixteen total days per month, and to reflect the change whereby mobile providers will no longer obtain a CON for the provision of services but rather hospitals and DTRCs will obtain the certificate of need.

The definition of "optimal utilization" has been revised to increase the capacity of a PET unit to 2,750 scans per year. The definition has also been revised to reflect that only dual modality PET units will be approved.

The definition of "PET scan service" has been revised to account for future possibilities of PET/MRI, or other dual modality PET units.

The standards relating to the projection of future need for PET services, contained in 111-2-2-.41(3)(a)1, have been revised as follows:

- the multiplication factor accounting for follow-up oncology scans and non-oncology scans has been decreased from 1.5 to 1.4 until January 1, 2010, when the multiplication factor will be based on a 2 year running average of the ratio of follow-up oncology scans and non-oncology scans to initial oncology scans.
- provisions have been added to the description of how to reflect the inventory of PET units to reflect that mobile units shall be counted as a percentage of the number of days providing services to sites in each planning region
- provisions have been added to clarify that any net numerical unmet need projection shall be rounded up to a unit, if the project is for .75 of a unit
- a provision has been added to clarify that a mobile unit may be approved to serve a planning area if the net numerical unmet need in the planning area is at least .032875 units, which amounts to 1 day per month.
- The rule has been clarified to provide that a mobile unit shall be approved for the number of days of use based on the percentage of unit remaining after application of the need methodology.

The standard relating to aggregate utilization at 111-2-2-.41(3)(a)2 has been modified to provide that units that do not report data or which did not exist in the survey year shall not be counted in the aggregate utilization. The aggregate utilization standard has been modified to 80% from 90%.

Former standards which were found in 111-2-2-.4(3)(b) have been deleted. These provisions related to the number of units and mobile units that

could be approved under the need methodology. These provisions have been modified as stated above and are included in 111-2-2-.41(3)(a)1((vii).

Provisions relating to exceptions to the need standard are now located in 111-2-2-.41(3)(b) and have been modified as follows:

- An additional exception has been added for sites served by mobile units who have performed at least 850 studies in a year such that the site will be able to seek the addition of a fixed unit and not be subject to the need standard.
- An exception to the need standard has been added to provide that hospitals that treat as inpatients persons who have been diagnosed with cancer and are undergoing treatment for the disease and whose application indicates they will contract with a mobile provider to offer PET service to their patients will not be subject to the rule need standards.

Former standards which were located at 111-2-2-.41(3)(d)1 have been deleted because the Department will require applications for dual modality PET units only.

At 111-2-2-.41(3)(d)2, provisions that would allow a facility to make a facility-wide commitment in lieu of a PET-specific commitment have been deleted.

At 111-2-2-.41(3)(e)4, standards allowing a physician director to document a 6-month training program in lieu of Board certification have been deleted.

A provision requiring documentation that the PET service has arrangements with board-certified interpreting physicians has been added at 111-2-2-.41(3)(e)5.

A standard has been added at 111-2-2-.41(3)(e)6 to ensure that technologists and physicians are certified by national accreditation bodies.

Provisions relating to affiliation, transfer, or referral agreements, located at 111-2-2-.41(3)(f)1, have been modified to require emergency transfer agreements with one or more acute care hospitals and to remove requirements for agreements with hospitals capable of offering a wide range of services including open heart surgery and surgical oncology.

111-2-2-.41 Specific Review Considerations for Positron Emission Tomography Units.

(1) Applicability.

(a) A certificate of need ~~will~~ shall be required for a new or expanded positron emission tomography (PET) unit.

(b) On or after January 1, 2008, the Department shall only consider and approve applications for dual modality PET units; stand-alone PET units shall not be approved.

(c) On or after January 1, 2008, an applicant for a mobile unit site shall be the hospital or DTRC which has entered into an agreement to receive mobile services. The actual mobile service provider shall not be the applicant. The hospital or DTRC that is serviced by the mobile provider shall be responsible for the provision of annual surveys and the provision of information to the Department.

(d) On or after January 1, 2008, a mobile provider shall be required to obtain a CON only if the fair market value or purchase price of the unit and any and all functionally related equipment exceeds the equipment threshold. If the fair market value or purchase price exceeds the equipment threshold, the mobile provider shall apply for a certificate of need under the general review considerations of 111-2-2-.09(1).

(e) A certificate of need obtained by a hospital or DTRC to offer mobile PET services shall be valid for the provision of mobile PET services only. A hospital or DTRC approved to offer mobile PET services must obtain a separate CON prior to offering fixed PET services.

(2) Definitions.

(a) "Health Planning Area" or "planning area" means the 13 geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed or mobile unit at a hospital or DTRC. ~~to an existing service or, in the case of a mobile unit, the addition of a new site not previously served by such mobile unit.~~ The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the equipment threshold at that time, the applicant shall

demonstrate compliance with or document a plan and agreement to comply with 111-2-2-41(3)(d), (e), (f), and (g).

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is operated by one or shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

~~1. The unit must be on site at each Facility identified in the application at least three (3) days per month.~~

~~12. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or twelve (12)~~ 16 (sixteen) total days per month.

~~23. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.~~

~~34. The applicant, if successful, For applications approved prior to January 1, 2008, a mobile provider is limited to providing service only for to those facilities approved in the mobile provider's application for CON. On or after January 1, 2008, a mobile provider may serve any hospital or DTRC that receives a certificate of need for mobile PET services, provided that no hospital or DTRC may be serviced by more than one mobile provider at a time. Additional facilities may be added to the service list only through an approved application for expansion. The applicant, if successful, may eliminate sites approved in the application; provided that all standards and criteria will still be met and the mobile unit provider and the site being eliminated jointly notify the department in writing of their intent to eliminate the site.~~

~~45. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.~~

(f) "Optimal Utilization" refers to scans per year and shall be defined as 4,500 2,750 PET scans per year ~~regardless of whether the diagnostic equipment is a standalone PET scanner or includes another component such as CT.~~ A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT or dual modality unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) Standards.

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by 50% to determine the projected number of patients diagnosed with cancer who might benefit from a scan.

(iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.

(iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by ~~4.5~~ 1.4 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services. On or after January 1, 2010, in lieu of multiplying by 1.4 each year, the Department shall use actual data from the previous 2 survey years to determine the multiplication factor by adding 1 to the ratio of cardiology, neurology and follow up oncology scans to the number of initial oncology scans.

(v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by ~~4,500~~ 2,750, which represents the optimal utilization of a unit. ~~Following the determination of whole numbers representing units, if the balance net numerical need in any Health Planning Area is at or above 75% of a unit (1125 individuals needing scans), the needed units shall be rounded up by one unit.~~

(vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of PET/CT or dual modality units currently existing or approved for use from the number of needed units. Mobile units shall be subtracted based on the number of days providing service to sites within a planning area in the most recent survey year divided by 365. Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

(vii) If the net numerical unmet need in any Health Planning Area is at or above 75% of a unit (approximately 2,062 individuals needing scans), the needed units shall be rounded up by one unit. If the balance net numerical need in any Health Planning Area is at or above 3.2875% of a unit (approximately 90 individuals needing scans), a mobile unit may be approved to serve the planning area. The maximum number of days a mobile unit may be approved to provide services in the planning area shall be determined using the following formula:

APPROVED DAYS PER YEAR

$$\frac{\text{APPROVED DAYS PER YEAR}}{365} \leq \text{NET NUMERICAL UNMET NEED}$$

2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all existing and approved units in that planning area that existed during the most recent survey year and that provided data to the Department for the most recent survey year shall equal or exceed 80% of optimal utilization for the most recent survey year.

~~(b)1. An applicant seeking an expansion or expanded service for a fixed unit may be approved only if all provisions of the need standards in 111-2-2-.41(3)(a) and all other standards in the Rules are met.~~

~~2. An applicant seeking an expansion or expanded service for a mobile unit may be approved, without meeting the need standards of 111-2-2-.41(3)(a)1.; provided that the planning area in which the applicant is seeking the expansion or expanded service shows a net numerical unmet need of more than 25% of a unit (375 individuals needing scans) but less than 75% of a unit (1125 individuals needing scans) and provided that all other standards are met and that the affiliation, transfer, or referral agreements provided pursuant to 111-2-2-.41(3)(f)1. are executed with a hospital or hospitals within the planning area in which the mobile unit seeks to expand.~~

~~(be) Exceptions to the need standards and requirements in (c)(1) (3)(a) may be granted by the Department:~~

~~1. for to an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility when the applicant has documented such a barrier:-~~

~~2. to an applicant seeking the addition of a fixed unit who has been served solely by a mobile PET when the applicant demonstrates that 850 studies have been performed on the mobile unit at the applicant's facility in the most recent survey year; and~~

~~3. to an applicant hospital that treats as inpatients persons who have been diagnosed with cancer and are undergoing treatment for the disease and who will offer the PET service to its patients through a contract with a mobile PET provider.~~

~~(cd)1. In considering applications joined for review, the Department may give favorable consideration to an applicant seeking approval for a service with a unit that includes both PET and CT scan capabilities.~~

2. In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(de) An applicant for a new or expanded service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five (5) percent of annual, adjusted gross revenues of the PET scan service or, ~~in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;~~

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(ef) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.

3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through contractual agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.

4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology ~~or has successfully completed a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.~~

5. Document that the PET services has arrangements with board-certified interpreting physician(s) that are licensed in the State of Georgia.

6. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, and radiology technologist, and operational personnel. Such personnel shall be certified by appropriate national accreditation bodies.

7. Document fully the safe and timely access to radiopharmaceuticals.

(fg) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

1. Document that the applicant provides, or has signed affiliation, transfer, or referral emergency transfer agreements and arrangements with one or more acute care hospital(s) located within the applicant's health planning area or in the case where the nearest acute care hospital is located in an adjacent health planning area, the nearest acute care hospital, and health care organizations that provide the following: comprehensive cancer services, including radiation oncology, medical oncology, and surgical oncology; open heart surgery; medical education; and services for persons with Alzheimer's or other dementias.

2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.

3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.

4. Document how medical emergencies will be managed in conformity with accepted medical practice.

(gh) An applicant for a new or expanded service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time and format requested by the department.

Authority O.C.G.A. §§. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled "Specific Review Considerations for Positron Emission Tomography Units" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.